JAN 21 2005

K04351V

EXHIBIT VII

510(k) SUMMARY

Allogran-N™

Applicant

Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person

J Stephen Bratt LL.B
Tel: +44 1782 338580
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1.	Classification Name:	Resorbable Calcium Salt Bone Void Filler Device
	Common/Usual Name:	Bone Void Filler
	Trade/Proprietary Name	Allogran-N™ - Bone Void Filler
	Product Code	MQV

Legally Marketed Predicate Devices

	Common/Usual Name	Manufacturer
1	Apatight™-HA Bone Graft Substitute	CERAbio LLC
2	ApaPore® Bone Graft Substitute	ApaTech Ltd

Device Description

Allogran-N™ Bone Void Filler is a hydroxyapatite bone graft substitute for the repair of bony defects. The granules are provided sterile for single patient use. When the Allogran-N™ granules are placed in direct contact with viable host bone, new bone grows in apposition to the surface of the implant, filling the pores with new bone during the healing process. The product is completely incorporated into the newly formed bone.

Intended Use / Indications

Allogran-N™ is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Allogran-N™ is packed into bony voids of the skeletal system (e.g., the spine, pelvis and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product is completely incorporated during the healing process. The Indications For Use statement is shown in Exhibit I.

Summary of Technology

Allogran-N™ is composed of a porous calcium salt, hydroxyapatite, equivalent to that contained in the predicate devices and to that in routine clinical use. The technologies employed in Allogran-N™ and the predicate devices are therefore substantially equivalent. Allogran-N™ is presented in granules in the same manner as the predicate devices. The indications, contraindications, risks and potential adverse events are the same and thus substantially equivalent.

Non Clinical Testing

Non clinical testing has been used to examine the chemical composition of Allogran-N™ which satisfies the standard for implantable hydroxyapatite.

Clinical Testing

Allogran-N™ has been regularly used clinically for the past 6 years and no adverse events have been reported in that time concerning the quality, safety or effectiveness of Allogran-N™.

Substantial Equivalence

Documentation provided demonstrates that Allogran-N™ is substantially equivalent to the legally marketed predicate devices in design, materials and indications.
Allogran-N™ is well tolerated and completely incorporated into the defect site into which it is implanted and is safe and effective when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2005

Mr. Stephen Bratt
Managing Director
Keele Science Park, Keele,
Staffordshire, England ST5 5NL

Re: K043514
Trade/Device Name: Allogran-N™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Bone Void Filler
Regulatory Class: II
Product Code: MQV
Dated: December 14, 2004
Received: December 20, 2004

Dear Mr. Bratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT I

INDICATIONS FOR USE

510(k) Number (if known): K043514

Device Name: Allogran-N™

Indications For Use:

Allogran-N™ is intended for use as a bone void filler or bone void substitute for bony voids or gaps that are not intrinsic to the stability of the bony structure.

Allogran-N™ is to be packed into bony voids or gaps in the skeletal system (e.g., the spine, pelvis and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. Allogran-N™ is completely incorporated with new bone during the healing process.

Prescription Use X OR Over-The-Counter use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043514